### THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today

- (1) was not written for publication in a law journal and
- (2) is not binding precedent of the Board.

#### UNITED STATES PATENT AND TRADEMARK OFFICE

# BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte VIRENDER K. SARIN, DARRYL R. ABSOLOM and SHANKER L. GUPTA

Application 07/808,075<sup>1</sup>

HEARD: June 12, 1998

Before WINTERS and WILLIAM F. SMITH, <u>Administrative Patent Judges</u>, and McKELVEY, <u>Senior Administrative Patent Judge</u>.

WILLIAM F. SMITH, <u>Administrative Patent Judge</u>.

## **DECISION ON APPEAL**

This is an appeal under 35 U.S.C. § 134 from the final rejection of claims 54 through 69. Claims 54, 60, 62, and 68 are illustrative of the subject matter on appeal and read as follow:

<sup>&</sup>lt;sup>1</sup> Application for patent filed December 10, 1991. According to appellants, this application is a continuation of Application 07/525,581, filed May 21, 1990 (abandoned).

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- 54. A purified composition of matter consisting of a covalently linked compound in physical admixture with at least one lipid, wherein said covalently linked compound consists of two parts and has the structural formula: FA-SPC, wherein -SP-C is protein selected from the group comprising human, porcine, canine and bovine surfactant associated protein C (SP-C) produced by chemical or enzymatic synthesis or recombinant DNA means, wherein said SP-C protein comprises a sequence of thirty-four (34) amino acids, said sequence containing eleven (11) valine amino acid residues, nine (9) of said valine residues being contained in two (2) adjacent polyvaline stretches, said polyvaline stretches having a first stretch of six adjacent valine amino acid residues and a second stretch of three adjacent valine amino acid residues separated from the stretch by two hydrophobic amino acid residues, said SP-C protein enhances surfactant-like activity of phospholipids in lungs of an animal, and is substantially resistant to protease, endoglycosidase F and collagenase enzymes, and wherein FA- is a single fatty acid selected from the group comprising fatty acids having a carbon chain length from two (2) to about twenty (20) carbon atoms and wherein said fatty acid is covalently attached to the amino end terminal amino acid residue of said SP-C.
- 60. A method for treating hyaline membrane disease or other syndromes associated with insufficient or abnormal surfactant material said method comprising administration of an effective amount of a surfactant composition to a patient in need of treatment, said surfactant composition consisting of at least FS-SPC and at least one lipid according to claim 54.
- 62. A purified composition of matter consisting of a covalently linked compound in physical admixture with at least one lipid, wherein said covalently linked compound consists of two parts and has the structural formula: FA-SPC, wherein -SP-C is protein selected from the group comprising human, porcine, canine and bovine surfactant associated protein C (SP-C) produced by chemical or enzymatic synthesis or recombinant DNA means, wherein said SP-C protein comprises a sequence of thirty-four (34) amino acids, said sequence containing eleven (11) valine amino acid residues, nine (9) of said valine residues being contained in two (2) adjacent polyvaline stretches, said polyvaline stretches having a first stretch of six adjacent valine amino acid residues and a second stretch of three adjacent valine amino acid residues separated from the first stretch by two hydrophobic amino acid residues, said SP-C protein enhances surfactant-like activity of phospholipids in lungs of an animal, and is

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substantially resistant to protease, endoglycosidase F and collagenase enzymes, and wherein FA- is a single fatty acid selected from the group comprising fatty acids having a carbon chain length from two (2) to about twenty (20) carbon atoms and wherein said fatty acid is covalently attached to the carboxyl end terminal amino acid residue of said SP-C.

68. A method for treating hyaline membrane disease or other syndromes associated with insufficient or abnormal surfactant material said method comprising administration of an effective amount of a surfactant composition to a patient in need of treatment, said surfactant composition consisting of at least FA-SPC and at least one lipid according to claim 62.

The references relied upon by the examiner are:

Sokol 4,234,475 Nov. 18, 1980

Whitsett et al. (Whitsett),

(PCT International Publication) WO87/06943<sup>2</sup> Nov. 19, 1987

Claims 54 through 69 stand rejected under 35 U.S.C. § 103 as unpatentable over Whitsett in view of Sokol. We reverse.

#### DISCUSSION

The claimed invention is directed in one aspect to a purified composition of matter which consists of a covalently linked compounded physical admixture with at least one lipid. The covalently linked compound consists of two parts, i.e., a specified surfactant associated protein C (SP-C) and a specified single fatty acid (FA). The fatty acid is covalently attached to either the amino end terminal amino acid residue of the SP-C (claim

<sup>&</sup>lt;sup>2</sup> The Whitsett patent document identifies as U.S. Application No. 07/860,239 as a priority application. Appellants state at page 6 of the appeal brief that that application issued as Patent No. 5,013,770. That is in error. That application ultimately issued as Patent No. 5,013,720.

54) or the carboxyl end terminal amino acid residue of the SP-C (claim 62).

A second aspect of the claimed invention is a method for treating hyaline membrane disease or other syndromes associated with insufficient or abnormal surfactant material which comprises administering an effective amount of the composition of either claim 54 or claim 62. See, e.g., claims 60 and 68.

Whitsett describes a purified composition of matter which comprises at least one lipid and an SP-C. The SP-C of Whitsett is <u>not</u> covalently linked with a fatty acid. See, e.g., the paragraph bridging pages 7-8 of Whitsett. The compositions of Whitsett are useful for treating hyaline membrane disease (HMD). See, e.g., the last full paragraph of page 9 of Whitsett.

Sokol describes a procedure for reacting a protein with an organic acid. The fatty acids which maybe used in the procedure of Sokol include some of those required by the claims on appeal. See, e.g., column 1, lines 46-68 of Sokol. The proteins used in the procedure of Sokol are described at column 1, lines 37-45 as follows. The products produced by Sokol are intended to be used "in cosmetics and other applications where contact with the skin occurs" (column 1, lines 9-14).

The examiner believes that it would have been obvious to one of ordinary skill in the art to modify the SP-C protein of Whitsett by covalently linking it with a fatty acid on

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the basis of the "generic disclosure of Sokol, which teaches that any surfactant protein can be combined with fatty acid component and that any such conjugated material will be useful as a surface active agents [sic]." We disagree.

As stated in <u>Pro-Mold & Tool Co. V. Great Lakes Plastics, Inc.</u>, 75 F.3d 1568, 1573, 37 USPQ2d 1626, 1629 (Fed. Cir. 1996):

It is well-established that before a conclusion of obviousness may be made based on a combination of references, there must have been a reason, suggestion, or motivation to lead an inventor to combine those references.

Here, apart from reference to appellants' disclosure of the present invention, we find no such reason, suggestion, or motivation which would have lead one of ordinary skill in the art to combine the disclosures of Whitsett and Sokol in the manner proposed by the examiner. The examiner has not identified why one of ordinary skill in the art would have any reason to modify the SP-C protein of Whitsett in the first place. Furthermore, the examiner's reliance solely upon the "generic" teaching of proteins in Sokol is highly suspect, especially after the decisions in In re Baird, 16 F.3d 380, 29 USPQ2d 1550 (Fed. Cir. 1994) and In re Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In short, it is our view that the "glue" which holds the proposed combination of references together comes only from appellants' disclosure, not the applied prior art.

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The decision of the examiner is reversed.

# **REVERSED**

SHERMAN D. WINTERS	)
Administrative Patent Judge	) ) )
WILLIAM F. SMITH Administrative Patent Judge	) BOARD OF PATENT ) APPEALS AND ) INTERFERENCES )
FRED E. McKELVEY, Senior	)

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